

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO 0579-0036

red with USDA

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

NOV 30 2000

2. HEADC include 21-R-0082, Cust Id 445

COLUMBIA UNIVERSITY
630 W 168TH ST
NEW YORK NEW YORK, NY 10032

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites)

Black Bldg & Eye Institute Annex, 630 W. 168th

New York, New York 10032

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	7	45	565	0	610
5. Cats	0	0	22	0	22
6. Guinea Pigs	0	51	105	0	156
7. Hamsters	0	0	35	0	35
8. Rabbits	12	79	95	0	174
9. Non-human Primates	6	0	42	0	42
10. Sheep	0	0	21	0	21
11. Pigs	0	0	44	0	44
12. Other Farm Animals					
Bovine	0	0	29	0	29
13. Other Animals					
Ferrets	0	24	0	0	24
Frogs	0	21	322	0	343

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL.
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGN:	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
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SUMMARY OF EXCEPTIONS

October 1, 1999 to September 31, 2000

1. In a single protocol, 12 rhesus monkeys must be chaired for periods greater than 12 hours and less than 24 hours. This is an exception to the standard set by the Laboratory Animal Welfare Act. The Act states that nonhuman primates must be given the opportunity for 1 hour of continuous unrestrained activity if more than 12 hours of restraint are required. Monkeys used in the protocol are chair-restrained approximately three to ten times per year. All animals are conditioned to this restraint to prevent any distress associated with chairing. The IACUC approved this restraint based upon the scientific requirements for continuous data collection.

2. Five ovariectomized female rhesus nonhuman primates will be transferred from a separate protocol to a new protocol that requires two additional survival surgeries over a time period of about two months. The purpose is to study endometriosis so that new treatments may be developed for humans suffering this disorder. The animals will not undergo any further major survival surgery after this protocol is completed. This is an exception to the standards set by the *Guide* and the Laboratory Animal Welfare Act (AWA), 9 CFR, § 2.31 (d)(x). The *Guide* states that multiple major survival surgical procedures on a single animal are discouraged but may be permitted if scientifically justified by the user and approved by the IACUC. The AWA standard states that no animal will be used in more than one major operative procedure unless justified for scientific reasons by the principal investigator, in writing and in special circumstances as determined by the USDA/APHIS Administrator. Both conditions were fulfilled. The USDA/APHIS Administrator approved the request for an exemption under 9 CFR, § 2.31(d)(x) to perform multiple survival surgeries on the five nonhuman primates used in the endometriosis study.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEI/ inc. 21-R-0168. Cust Id 402

S T S DUOTEK, INC.
7500 W. HENRIETTA ROAD
RUSH, NY 14543

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

7500 W. Henrietta Rd Rush NY 14543

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		496		293	3427
7. Hamsters					
8. Rabbits		258	218		476
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U S C Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11-30-00

A (AUG 97)

(OCT 88), which is obsolete)

PART 1 - HEADQUARTERS



**STERILIZATION
TECHNICAL
SERVICES**

division of STS duoTEK, Inc.

7500 West Henrietta Rd. • Rush, New York 14543 • Tel: 716-533-1672 • Fax: 716-533-1796

Annual Report Addendum, 2000, Facility No. 21-R-168

Category E Explanation

The Guinea Pig (b)(4) Test is a procedure which determines the allergenicity of materials. This study is required by the FDA Modified ISO 10993-1 matrix for preclinical evaluations of Class II and III medical devices. In this procedure, an adjuvant and saline extract are injected intradermally. The adjuvant enhances the immune response and does result in lesion formation at the injection site. These lesions, ranging in size from (b)(4) (b)(4) are not treated due to the possible interference or enhancement of the sensitization response. In order to determine the health status of these animals, daily observations are performed and animal health technical personnel evaluate the sites. Any abnormal findings are reported to the Attending Veterinarian for assessment. During this period, 10/01/99 to 9/30/00, none of the 2931 guinea pigs used in this evaluation required additional veterinary care for problems related to the lesions.

In order to address pain and distress, the Attending Veterinarian researched analgesics and an appropriate oral medication which would not affect the animals' fluid intake was not available. The nature of the Guinea Pig (b)(4) Test negates the use of topical analgesia. We also performed weight trends and the animals exhibited weight gain throughout the test procedure. The animals ambulated normally and only vocalized when handled (as is the case with untreated guinea pigs).

EAB

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 21-R-0168	CUSTOMER NO. 402	FORM APPROVED OMB NO 0579-0036
2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)		
S T S DUOTEK, INC. 7500 W. HENRIETTA ROAD RUSH, NY 14543 (716) 533-1672		

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)
12-03-2001 RCV

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sides)

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

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4. Dogs					
5. Cats					
6. Guinea Pigs	90	338		2066	2404
7. Hamsters					
8. Rabbits		134	239		373
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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**CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)**

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

DATE SIGNED

11/30/01

HEADQUARTERS

Signature

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number: 21-R-0168
Customer Number: 402
Facility: S T S DUOTEK, INC.
7500 W. HENRIETTA ROAD
RUSH, NY 14543
(716) 533-1672

STERILIZATION TECH SERVICES
7500 W. HENRIETTA RD
RUSH, NY 14543



**STERILIZATION
TECHNICAL
SERVICES**

division of STS duoTEK, Inc.

7500 West Henrietta Rd. • Rush, New York 14543 • Tel: 716-533-1672 • Fax: 716-533-1796

Annual Report Addendum, 2001, Facility No. 21-R-168
Category E Explanation

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In order to address pain and distress, the Attending Veterinarian researched analgesics and an appropriate oral medication which would not affect the animals' fluid intake was not available. The nature of the Guinea Pig (b)(4) Test negates the use of topical analgesia. We also performed weight trends and the animals exhibited weight gain throughout the test procedure. The animals ambulated normally and only vocalized when handled (as is the case with untreated guinea pigs).